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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,942	12/10/2003	Edward C. Benzel	AXM-6666	6468
26294 7590 02/02/2009 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114				
			EXAMINER	
			HARVEY, JULIANNA NANCY	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/731,942

Applicant(s)

BENZEL ET AL.

Examiner

Julianna N. Harvey

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-40 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-16, 18-23 and 25-33 is/are rejected.
- 7) ☒ Claim(s) 3, 17 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

In the 6 August 2008 Office Action, the examiner had indicated claims 4 and 18 as allowable over the prior art. Upon further search and consideration, the examiner has determined that these claims are not allowable over the prior art.

Claim Objections

In view of Applicant's cancellation of claim 34, the objection to this claim, as stated in the 6 August 2008 Office Action, has been withdrawn.

Claim Rejections - 35 USC § 112

In view of Applicant's cancellation of claim 34, the rejection of this claim, as stated in the 6 August 2008 Office Action, has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-8, 10-16, 19-22, and 25-33 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Ross et al. (US 2003/0187506 A1).

Regarding **claim 1**, Ross et al. disclose a method for replacing a damaged spinal disc between first and second vertebrae of a spinal column comprising: connecting a first mounting member ("14") with the first vertebra of the spinal column; and moving an artificial disc between the first and second vertebrae and into engagement with the first mounting member to guide the artificial disc into position between the first and second vertebrae, the artificial disc including a resilient core ("20") having a first surface and a second surface, a first retaining member ("22") fixedly connected to the first surface of the resilient core, and a second retaining member ("24") fixedly connected to the second surface of the resilient core, the first retaining member having an outer surface engageable with the first vertebra of the spinal column and an inner surface facing the first surface of the resilient core, the second retaining member having an outer surface engageable with the second vertebra of the spinal column and an inner surface facing the second surface of the resilient core (paras. 0028-0029 and 0046; Figs. 3A-B and 7).

Regarding **claim 2**, Ross et al. disclose engaging the first mounting member with a guide ("30") on the first retaining member to guide movement of the first retaining member into position between the first and second vertebrae (paras. 0041 and 0046; Figs. 3A-B and 7).

Regarding **claim 5**, Ross et al. disclose engaging the first mounting member with a stop (side surface of "30") on the first retaining member to prevent relative movement between the first retaining member and the first mounting member in

a first direction (paras. 0041 and 0046; Figs. 3A-B). Regarding **claim 6**, Ross et al. disclose guiding movement of the first retaining member relative to the first mounting member in a second direction extending transverse to the first direction (paras. 0041 and 0046). Regarding **claim 7**, Ross et al. disclose guiding movement of the first mounting member into an opening in the first retaining member (paras. 0041 and 0046; Figs. 3A-B). Regarding **claim 8**, Ross et al. disclose that connecting the first mounting member with the first vertebra includes engaging the first mounting member with a surgical tool for connecting the first mounting member to the first vertebra (para. 0047). Regarding **claim 10**, Ross et al. disclose spacing an inner surface of the first mounting member that faces the core from the core (para. 0041 discusses reversing the dovetails of "30"; para. 0046). Regarding **claim 11**, Ross et al. disclose connecting the artificial disc to the first mounting member (para. 0041). Regarding **claim 12**, Ross et al. disclose that connecting the artificial disc to the first mounting member includes preventing movement of the first mounting member relative to the artificial disc (para. 0041). Regarding **claim 13**, Ross et al. disclose that preventing movement of the first mounting member relative to the artificial disc includes connecting the artificial disc to the first mounting member with an interference fit (para. 0041). Regarding **claim 14**, Ross et al. disclose that connecting the artificial disc to the first mounting member with an interference fit includes engaging a frustoconical surface on the artificial disc with a frustoconical surface on the first mounting member (para. 0041; Figs. 3A-B). Regarding **claim 15**, Ross et al. disclose connecting a second mounting member ("16") to the second vertebra and that moving the artificial disc between the first and second

vertebrae includes engaging the second mounting member with the artificial disc to guide movement of the artificial disc into position between the first and second vertebrae (para. 0046; Figs. 3A-B and 7). Regarding **claim 16**, Ross et al. disclose engaging the first mounting member with a first guide ("30") on the first retaining member to guide movement of the first retaining member into position between the first and second vertebrae and engaging the second mounting member with a second guide ("30") on the second retaining member to guide movement of the second retaining member into position between the first and second vertebrae (paras. 0041 and 0046; Figs. 3A-B and 7). Regarding **claim 19**, Ross et al. disclose engaging the first mounting member with a first stop (side surface of "30") on the first retaining member to prevent relative movement between the first retaining member and the first mounting member in a first direction and engaging the second mounting member with a second stop (side surface of "30") on the second retaining member to prevent relative movement between the second retaining member and the second mounting member in the first direction (paras. 0041 and 0046; Figs. 3A-B). Regarding **claim 20**, Ross et al. disclose guiding movement of the first retaining member relative to the first mounting member in a direction extending transverse to the first direction and guiding movement of the second retaining member relative to the second mounting member in a direction extending transverse to the first direction (paras. 0041 and 0046). Regarding **claim 21**, Ross et al. disclose guiding movement of the first mounting member into an opening in the first retaining member and guiding movement of the second mounting member into an opening in the second retaining member (paras. 0041 and 0046; Figs. 3A-B).

Regarding **claim 22**, Ross et al. disclose that connecting the first mounting member with the first vertebra includes connecting the first mounting member with a surgical tool for connecting the first mounting member to the first vertebra and connecting the second mounting member with the second vertebra includes connecting the second mounting member with the surgical tool for connecting the second mounting member to the second vertebra (para. 0047). Regarding **claim 25**, Ross et al. disclose spacing an inner surface of the first mounting member that faces the core from the core and spacing an inner surface of the second mounting member that faces the core from the core (para. 0041 discusses reversing the dovetails "30"; para. 0046). Regarding **claim 26**, Ross et al. disclose connecting the artificial disc to the first and second mounting members (para. 0041). Regarding **claim 27**, Ross et al. disclose that connecting the artificial disc to the first and second mounting members includes preventing movement of the first and second mounting members relative to the artificial disc (para. 0041). Regarding **claim 28**, Ross et al. disclose that preventing movement of the first and second mounting members relative to the artificial disc includes connecting the artificial disc to the first and second mounting members with interference fits (para. 0041). Regarding **claim 29**, Ross et al. disclose that connecting the artificial disc to the first and second mounting members with interference fits includes engaging frustoconical surfaces on the artificial disc with frustoconical surfaces on the first and second mounting members (para. 0041; Figs. 3A-B). Regarding **claim 30**, Ross et al. disclose that moving the artificial disc between the first and second vertebrae includes connecting a surgical tool to a first portion of the first retaining member (para. 0047).

Regarding **claim 31**, Ross et al. disclose that moving the artificial disc between the first and second vertebrae includes connecting the surgical tool to a first portion of the second retaining member (para. 0047). Regarding **claim 32**, Ross et al. disclose that connecting the surgical tool to the first portion of the first retaining member includes extending a first portion of the surgical tool into a first opening in the first portion of the first retaining member (para. 0047). Regarding **claim 33**, Ross et al. disclose that connecting the surgical tool to the first portion of the second retaining member includes extending a second portion of the surgical tool into a first opening in the first portion of the second retaining member (para. 0047).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (US 2003/0187506 A1). Regarding **claim 4**, Ross et al. disclose engaging the first mounting member with a first guide ("30") on the first retaining member to guide movement of the first retaining member into position between the first and second vertebrae (paras. 0041 and 0046; Figs. 3A-B and 7). Regarding **claim 18**, Ross et al. disclose engaging the first mounting member with a first guide ("30") on the first retaining member to guide movement of the first retaining member into position

between the first and second vertebrae and engaging the second mounting member with a third guide ("30") on the second retaining member to guide movement of the second retaining member into position between the first and second vertebrae (paras. 0041 and 0046; Figs. 3A-B and 7). Ross et al. fail to disclose engaging the first mounting member with a second guide extending parallel to the first guide on the first retaining member (**claim 4**), that engaging the first mounting member with the surgical tool includes extending a portion of the surgical tool into a recess in the first mounting member (**claim 9**), and engaging the first mounting member with a second guide extending parallel to the first guide on the first retaining member and engaging the second mounting member with a fourth guide extending parallel to the third guide on the second retaining member (**claim 18**). However, Ross et al. indicate that the artificial disc can include features that are effective to permit connection to a surgical tool and then suggests such a connection with respect to the retaining members includes extending a portion of the surgical tool into recesses in the retaining members (para. 0047). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the first retaining member of Ross et al. with a second guide parallel to the first guide (**claim 4**) and the first retaining member of Ross et al. with a second guide parallel to the first guide and the second retaining member of Ross et al. with a fourth guide parallel to the third guide (**claim 18**), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the first

mounting member with a recess to receive the surgical tool (**claim 9**) as doing so provides an effective connection between the mounting member and the surgical tool.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (US 2003/0187506 A1) in view of Kambin (US 5,584,887 A). Ross et al. disclose the claimed invention except moving the first and second mounting members away from each other to connect the first and second mounting members to the first and second vertebrae. However, it is obvious that this occurs as manufacturers, when packaging products, group like pieces together. Kambin illustrates this showing a surgical kit containing an implant comprising numerous mounting members ("1") which are grouped together in the kit. Kambin also shows that the mounting members are connected to first and second vertebrae ("1" and "60") (Figs. 9 and 16-17). As such, some time during insertion, it is obvious that a first and second mounting member are moved away from each other to connect to the first and second vertebrae. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Ross et al. artificial disc, including mounting members, in a kit with like pieces grouped together such that the surgeon would move the first and second mounting members away from each other to connect the first and second mounting members to the first and second vertebrae, as suggested by Kambin, as such a kit enhances efficiency during the surgical procedure.

Allowable Subject Matter

Claims 35-40 are allowed.

Claims 3, 17, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., until 2:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733